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U.S. APPLICATION NUMBER NO. 10/471,758	FIRST NAMED APPLICANT Naftali Tishby	ATTY. DOCKET NO. 26874
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 Suite 207  
 Arlington, VA 22202

INTERNATIONAL APPLICATION NO. PCT/IL02/00278	
I.A. FILING DATE 04/04/2002	PRIORITY DATE 03/30/2001

CONFIRMATION NO. 3610  
 371 FORMALITIES LETTER



\*OC000000012033488\*

Date Mailed: 03/05/2004

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 09/26/2003
- Copy of the International Search Report filed on 09/26/2003
- Oath or Declaration filed on 09/26/2003
- Small Entity Statement filed on 09/26/2003
- Request for Immediate Examination filed on 09/26/2003
- U.S. Basic National Fees filed on 09/26/2003
- Priority Documents filed on 09/26/2003
- Power of Attorney filed on 09/26/2003

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
  - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- \$65 Surcharge for providing the oath or declaration later than 30 months from the priority date (37 CFR 1.492(e)) is required.

The following items **MUST** be furnished within the period set forth below:

- The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reason(s):

- This application does not contain a "Sequence Listing" as a separate part of the disclosure on paper copy or compact disc, as required by 37 CFR 1.821(c) and PCT Rule 5.2(a).
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e) and PCT Rule 13ter.1(a)(ii).
- APPLICANT MUST PROVIDE:
  - An initial or substitute computer readable form (CRF) of the "Sequence Listing."
  - An initial or substitute paper copy or compact disc of the "Sequence Listing," as well as an amendment directing its entry into the specification.
- For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:
  - For Rules Interpretation, call (703) 308-4216
  - To Purchase PatentIn Software, call (703) 306-2600
  - For PatentIn Software Program Help, call (703) 306-4119 or e-mail at [patin21help@uspto.gov](mailto:patin21help@uspto.gov) or [patin3help@uspto.gov](mailto:patin3help@uspto.gov)
- **\$65** Late oath or declaration Surcharge.

#### SUMMARY OF FEES DUE:

Total additional fees required for this application is **\$65** for a Small Entity:

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

BARBARA A CAMPBELL

Telephone: (703) 305-3631

#### PART 2 - OFFICE COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/471,758	PCT/IL02/00278	26874

It is Applicant(s)' opinion that the claims presently on file patently distinguish the present invention from each of these references. The above references are being cited only in the interests of candor and without any admission that they constitute statutory prior art or contain matter which anticipates the invention or which would render the same obvious, either singly or in a combination, to a person of ordinary skill in the art.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 50-1047.

Respectfully submitted,



Keum J. Park  
Attorney for Applicant(s)  
Reg. No. 42,059  
Tel. 908-518-7700  
Fax: 908-518-7795

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Enclosures: ☒ PTO/SB/08  
☒ References; US patents omitted, as not required  
☐ Foreign Search Report  
☐ Other:

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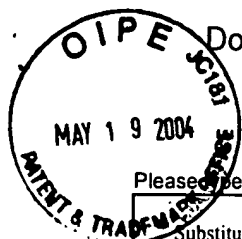
Substitute for form 1449A/PTO		<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		Application Number	10/748,117	
		Filing Date	12/29/2003	
		First Named Inventor	Derek O'Hagan et al.	
		Group Art Unit	1645	
		Examiner Name	Unassigned	
Sheet	1	of	Attorney Docket Number	PP20038.003

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM- DD-YYYY
		Number	Class/Subclass		
	1.	US2002/0183251A1	514/12	Xu et al.	12/05/2002
	2.	US2002/0136776 A1	424/501	Fang et al.	09/26/2002
	3.	US2002/0002272A1	530/388.3	Houghton et al.	01/03/2002
	4.	6,465,633 B1	536/23.7	Skeiky	10/15/2002
	5.	6,451,325 B1	424/283.1	Van Nest et al.	09/17/2002
	6.	6,372,227 B1	424/283.1	Garcon et al.	04/16/2002
	7.	6,355,257 B1	424/278.1	Johnson et al.	03/12/2002
	8.	6,303,347 B1	435/101	Johnson et al.	10/16/2001
	9.	6,290,973 B1	424/278.1	Hawkins et al.	09/18/2001
	10.	6,086,901	424/283.1	O'Hagan et al.	07/11/2000
	11.	US2003/0170273A1	424/225.1	O'Hagan et al.	09/11/2003
	12.	US2003/0138453A1	424/199.1	O'Hagan et al.	07/24/2003

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T
		Office <sup>3</sup>	Number <sup>4</sup>	Class/Subclass			
	1.	WO	02/26209 A2	A61K 9/00	Chiron Corporation	04/04/2002	
	2.	WO	00/50006	A61K 9/107	Chiron Corporation	08/31/2000	
	3.	WO	98/33487	A61K 9/16	Chiron Corporation	08/06/1998	
	4.	WO	02/03961 A1	A61K 9/16	Corixa Corporation	01/17/2002	
	5.	WO	00/06123	A61K 9/16	Chiron Corporation	02/10/2000	
	6.	WO	01/36599 A1	C12N 5/06	Chiron Corporation	05/25/2001	
	7.	WO	02/26212 A2	A61K 9/16	Chiron Corporation	04/04/2002	
	8.	WO	01/81609 A2	C12N 15/86	Chiron Corporation	11/01/2001	
	9.	WO	03/028661 A2	A61K	Chiron Corporation	04/10/2003	
	10.	WO	03/070909 A2	C12N	Chiron Corporation	08/28/2003	
Examiner Signature					Date Considered		

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation, if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.



Docket No.: PP20038.003

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/748,117
				Filing Date	12/29/2003
				First Named Inventor	Derek O'Hagan et al.
				Group Art Unit	1645
				Examiner Name	Unassigned
Sheet	2	of	2	Attorney Docket Number	PP20038.003

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1.	M. Briones et al., "The Preparation, Characterization, and Evaluation of Cationic Microparticles for DNA Vaccine Therapy," <i>Pharmaceutical Research</i> , Vol. 18, no. 5, 2001, pp. 709-712.	
	2.	J. Kazzaz et al., "Novel Anionic Microparticles Are a Potent Adjuvant for the Induction of Cytotoxic T Lymphocytes Against Recombinant p55 Gag from HIV-1," <i>Journal of Controlled Release</i> , Vol. 67, 2000, pp. 347-356.	
	3.	K.S. Denis-Mize et al., "Plasmid DNA Adsorbed onto Cationic Microparticles Mediates Target Gene Expression and Antigen Presentation by Dendritic Cells," <i>Gene Therapy</i> , Vol. 7, 2000, pp. 2105-2112.	
	4.	Manmohan Singh et al., "Cationic Microparticles Are an Effective Delivery System for Immune Stimulatory CpG DNA," <i>Pharmaceutical Research</i> , Vol. 18, no. 10, October 2001, pp. 1476-1479.	
	5.	Manmohan Singh et al., "Cationic Microparticles: A Potent Delivery System for DNA Vaccines," <i>Proceedings of the National Academy of Science USA</i> , Vol. 97, no. 2, Jan. 18, 2000, pp. 811-816.	
	6.	Manmohan Singh et al., "Mucosal Immunization with HIV-1 Gag DNA on Cationic Microparticles Prolongs Gene Expression and Enhances Local and Systemic Immunity," <i>Vaccine</i> , Vol. 20, 2002, pp. 594-602.	
	7.	Derek O'Hagan et al., "Induction of Potent Immune Responses by Cationic Microparticles with Adsorbed Human Immunodeficiency Virus DNA Vaccines," <i>Journal of Virology</i> , Vol. 75, no. 19, Oct. 2001, pp. 9037-9043.	
	8.	Hawkins, Lynn D. et al., "A Novel Class of Endotoxin Receptor Agonists with Simplified Structure, Toll-Like Receptor 4-Dependent Immunostimulatory Action, and Adjuvant Activity," <i>Journal of Pharmacology and Experimental Therapeutics</i> , Vol. 300, no. 2, 2002, pp. 655-661.	
	9.	Johnson, David A., "Synthesis and Biological Evaluation of A New Class of Vaccine Adjuvants: Aminoalkyl Glucosaminide 4-Phosphates (AGPs)," <i>Bioorganic &amp; Medicinal Chemistry Letters</i> , Vol. 9, 1999, pp. 2273-2278.	

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation, if not in conformance and not considered. Include copy of this form with next communication to applicant.

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